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EXAMINER	
MI, QIUWEN	

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1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,662	TAAL ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-10 are pending.

Applicant's election with traverse of Group I, claims 1-2, and 5-9, in the reply filed on 1/23/09 is acknowledged. The traversal is on the ground(s) that claim 3 of Group II and claim 1 of Group II has a similar technical feature and claims 1-9 should be examined in the instant application. This is found persuasive, therefore, the restriction between Group I and II are withdrawn, only claim 10 is withdrawn from consideration.

Claims 1-9 are examined on the merits.

Specification/Abstract Objections

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant is required to delete "The invention relates to" on line 1 of the Abstract to be more clear and concise. The first letter of "a" in line 1 should be capitalized after the deletion.

Claim Objections

Claims 1-9 are objected to because of the following informalities:

Claims 1-9 recite “Kit” in line 1, which may lead to ambiguity. Applicant is suggested to recite "A kit" to be more accurate.

Claims 1-4 recite “Melissa Officinalis…Eleutherococcus senticosus…Avena sativa…Battota Nigra…Glycyrrhiza glabra…Uncaria Tomentosa…”, which is improper. Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

All other cited claims depend directly or indirectly from objected claims and are, therefore, also, objected for the reasons set forth above.

Claim Rejections –35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, asthma, tale and mane eczema, does not reasonably provide enablement for treating any disorders in mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d

1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is drawn to a kit for the treatment of disorders in mammals.

The Merck manual indicates that there are plethora of disorders known, for example, Arteriovenous fistula, pleural effusion, Charcot's joints, polyarteritis nodosa, ganglia, Horner's syndrome, temporomandibular joint, Klenbock's disease, narcolepsy, dystonia, multiple system atrophy, obsessive-compulsive disorder, anal fissure, ischemic hepatitis, cholecystitis, tubulointerstitial nephritis, renal vein thrombosis, cystinuria, anorexia nervosa, pulpitis, hypolipoproteinemia, polycythemia vera, galactorrhea, virillization, to name just a few (see Disorders from Merck manual, pp. 1-24, accessed on 2/17/09). For example, Alzheimer's disease according to the Merck manual is chronic, global, usually irreversible deterioration of cognition. The main types of Alzheimer's disease are: vascular dementia, Lewy body dementia, frontal-temporal dementias, and HIV-associated dementia (See Dementia from Merck manual, pp. 1-3, accessed on 2/17/09). Furthermore, Alzheimer's disease causes progressive cognitive deterioration and is characterized by senile plaques, beta-amyloid deposits, and neurofibrillary tangles in the cerebral cortex and subcortical gray matter. Furthermore, the Merck manual indicates that most cases are sporadic, with late onset and unclear etiology. Since symptoms,

signs are similar to those of other dementia, distinguishing Alzheimer's disease from other dementias is difficult (see Alzheimer's disease from Merck manual, pp. 1-21, accessed on 2/17/09).

(2) The state of the prior art:

The claims imply that by administering the claimed kit to a mammal, any disorders can be treated. This is contrasted with the finding of the prior art. For instance, Walker (Personality, coping and sex as psychosocial aspects of psoriatic arthropathy, Dermatology and Psychosomatics, (2003) Vol. 4, No. 1, pp. 27-32) teaches that psoriasis is a chronic, currently incurable skin disease affecting 2-3% of the population and is associated with problems in body image and self-esteem and feelings of stigma and shame (see Abstract). In addition, Yu et al (Effects of long-term oral administration of polymeric microcapsules containing tyrosinase on maintaining decreased systemic tyrosine levels in rats, Journal of pharmaceutical sciences, (2004 Apr) Vol. 93, No. 4, pp. 831-7) teach that there is no effective treatment for melanoma, a fatal skin cancer occurring with increasing frequency (see Abstract). Further more, Cleaver (Defective repair replication of DNA in xeroderma pig-mentosum, NATURE [LONDON], (1968) Vol. 218, No. 5142, pp. 652-656) teaches that patients with xeroderma pigmentosum develop fatal skin cancers when exposed to sunlight (see Abstract).

(3) The relative skill of those in the art:

The relative skill in the art is high. The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g.M.D., Ph.D., Pharm. D. or combinations thereof).

(4) The predictability or unpredictability of the art:

Applicant's activity is based on treating any type of disorders. Treating any type of disorders is unpredictable in the art. For instance, Jullien (A new treatment for psoriasis, Nouvelles Dermatologiques, (Apr 2006) Vol. 25, No. 4, pp. 264-272) teaches that psoriasis is an incurable, life-long, immune-mediated disease with cutaneous manifestations, which requires continuons disease management over an extended period of time. The risk of cumulative toxicity, inconsistent treatment efficacy, and inconvenience, have limited the usefulness of traditional therapies for the long-term control of psoriasis (see Abstract). Another example, in terms of treating cancer, the co-relation between in vitro and in vivo system are unpredictable in the art. Those of skill in the art recognize that in vitro assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in- vitro assay does not permit a single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability. In vitro assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type (Freshney, Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost.

(5) The breadth of the claims:

The invention is drawn to a kit for treating any disorders in mammals. It implies that by administering the claimed kit, all kinds of disorders, such as Arteriovenous fistula, pleural effusion, Charcot's joints, polyarteritis nodosa, ganglia, Horner's syndrome, temporomandibular joint, Klenbock's disease, narcolepsy, dystonia, multiple system atrophy, obsessive-compulsive disorder, anal fissure, ischemic hepatitis, cholecystitis, tubulointerstitial nephritis, renal vein thrombosis, cystinuria, anorexia nervosa, pulpitis, hypolipoproteinemia, polycythemia vera, galactorrhea, virillization, and Alzheimer's disease can be treated.

(6) The amount of direction or guidance presented.

The specification has not provided guidance on treating a representative number of all kinds of disorders by using the claimed kit.

(7) The presence or absence of working examples:

There is no working example regarding how to treat a representative number of all kinds of disorders by using the claimed kit. The specification only provides examples for treating lupus (page 7, Example 1), tale and mane eczema (pages 7-8, Example 2).

(8) The quantity of experimentation necessary:

Since treating all kinds of disorders by using the claimed kit is such a complex issue, the state of the art has not been able to treat all kinds of disorders. Plus the claimed kit has not showed to treat all kinds of disorders, and the specification has not provided any guidance regarding how to treat all kinds of disorders by using the claimed kit, the quantity of experimentation is undue. Further more, in order to treat all kinds of disorders, the treatment regimen must be identified. Since the Applicant have not provided the appropriate time frame

and dosage at which the extract should be administered to treat all kinds of disorders, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine if the claimed kit would be effective in treating all kinds of disorders.

Based on the aforementioned reasons the Examiner concludes that the specification, while being enabling for the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, asthma, tale and mane eczema, does not reasonably provide enablement for the treatment of all kinds of disorders without requiring the ordinary skilled artisan to undertake undue experimentation. Since the state of the art is highly unpredictable and requires much greater guidance for an ordinary skilled artisan to effectively treat all kinds of disorders. Burdensome experimentation, such as clinical studies would necessarily be required of the ordinary skilled artisan to establish the treatment for all kinds of disorders.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For instance, Claim 1 recites “a first composition including leaves of Melissa officinalis, or parts thereof”, and it is uncertain what Applicant means by that “parts thereof”. Does it mean any parts of the Melissa officinalis plant can be used in the first composition, such as roots, flowers, barks, seeds? If that is the situation, then the recitation of “roots of Glycyrrhiza glabra”,

"roots of Uncaria tomentosa" seems unnecessary, as any parts of the plant will do. For the same reason, it applies to 2nd to 6th compositions.

Claim 9 recites "tale and mane eczema" in claim 9, line 3, and it is not clear what Applicant means by "tale eczema", does Applicant mean to say "tail eczema"?

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Flynn (The herbal management of stress, Austrilian journal of medical herbalism, 1996: 8 (1): 15-18), Widy-Tyszkiewicz et al (A randomized double blind study of sedative effects of phytotherapeutic containing valerian, hops, balm and motherwort versus placebo, Herba polonica, (1997) Vol. 43, No. 2, pp. 154-159), Singh et al (Therapeutic potential of Kava in the treatment of anxiety disorders, CNS drugs 2002: 16 (11): 731-743), McClung (US

6579543) and Sandoval (Cat's claw (Uncaria tomentosa) protects against oxidative stress and indomethacin-induced intestinal inflammation, Gastroenterology, 1997; 112 (4 suppl.): A1081).

Flynn teaches herbs offer an extremely successful way to manage both physiological and psychological response to stress. Avena sativa is great to use in cases of ongoning stress to feed and restore the nervous system (page 16, 1st column, 2nd paragraph). Flynn also teaches Avena feeds the nervous system in an active sense as a nutrient, and is therefore useful as a long term measure in any stress condition (page 17, 1st column, 3rd paragraph) (thus the third composition). Glycyrrhiza glabra has wide application to stress, both in adrenal support and for stress-induced problems (page 16, 1st column, 4th paragraph) (thus the fifth composition). Eleutherococcus senticosus studies have shown it to increase both mental and physical stamina during periods of stress by up to 70%, and it also counters the debility and stress of chronic disease and surgery (page 16, 2nd column, last paragraph) (thus the second composition).

Flynn does not teach using Avena sativa, Glycyrrhiza glabra, and Eleutherococcus senticosus in one kit, neither does Flynn teach the incorporation of Melissa officinalis, Piper methysticum, Ballota nigra, or Uncaria tomentosa into the kit; neither does Flynn teach the pharmaceutical form of tablet or capsule.

Widy-Tyszkiewicz et al teach a commercially available anti-stress tablets (thus at least one composition is in the form of a capsule or tablet) containing 50 mg of balm leaves (Melissa officinalis) etc (page 154, 2nd paragraph from the bottom). It is deemed that a tablet contains a pharmaceutically acceptable carrier such as a binding agent.

Singh et al teach kava (Piper methysticum) has been shown to be effective in mild to moderate cases of anxiety. Its biological activity, due to a mixture of compounds called

kavalactonse, are reported to include antistress properties etc (see Abstract) (thus a fourth composition in claim 3).

McClung teaches an antidepressant/anti-anxiety/anti-stress compound is selected from the group consisting of black horehound etc (the same as Ballota nigra) (col 3, lines 45-55),

Sandoval teaches Uncaria tomentosa protects cells against oxidative stress (see Abstract) (thus sixth composition).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for anti-stress activity. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for anti-stress activity.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for anti-stress activity. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re* Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The

differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants'

invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have anti-stress activity, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Flynn, Widy-Tyszkiewicz et al, Singh et al, McClung, and Sandoval since all of them teach compositions for anti-stress activity individually in the art. Since all the compositions yielded beneficial results for anti-stress activity, one of ordinary skill in the art would have been motivated to make the modifications to combine the references together. Regarding the limitation to the amount of the composition in the kit, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use to treat lupus, multiple scelerosis, rheumatoid arthritis, rheumatism, osteoporosis, asthma in humans or tale and mane eczema in horses. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 9.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655